

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DEPARTMENTAL APPEALS BOARD

**DECISION OF MEDICARE APPEALS COUNCIL**  
**Docket Number: M-11-2534 (formerly M-11-358)**

**In the case of**

**Claim for**

Robert D. Lesser, M.D.  
& Associates  
\_\_\_\_\_  
(Appellant)

Supplementary Medical  
Insurance Benefits (Part B)  
\_\_\_\_\_

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\_\_\_\_\_  
(Beneficiaries)

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\_\_\_\_\_  
(HIC Numbers)

Pinnacle Business Solutions  
\_\_\_\_\_  
(Contractor)

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\_\_\_\_\_  
(ALJ Appeal Number)

The Medicare Appeals Council (Council) has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated July 14, 2011, because it contains errors of law material to the outcome of the claims. See 42 C.F.R. § 405.1110. The ALJ's "partially favorable" decision concerned Medicare's recovery of an extrapolated overpayment based upon a post-payment audit of the appellant's claims for certain physician and outpatient laboratory services with dates of service on January 1, 2005, through December 31, 2006. In that decision, the ALJ: held that the dates of service occurring on August 29, 2005, through January 31, 2006, must be removed from audit consideration due to the state of emergency caused by Hurricane Katrina, pursuant to the Secretary's section 1135 waiver; set aside the extrapolated overpayment on the basis that the Zone Program Integrity Contractor (ZPIC) utilized invalid sampling methodology; individually considered each of the 108 sample claims remaining at issue; determined that some of the services comprising the sample were reasonable and necessary, and thus, covered by Medicare; held the appellant liable for the non-covered services pursuant to section 1879 of the Social Security Act (Act); and waived the appellant's liability for overpayments arising from January 1, 2005, through August 28, 2005, dates of service pursuant to section 1870 of the Act. The appellant has not requested review of this decision.

On September 9, 2011, the AdQIC, acting on behalf of the Centers for Medicare & Medicaid Services (CMS), filed a referral for own motion review by the Council.<sup>1</sup> See 42 C.F.R. § 405.1110. The Council enters the CMS referral into the record as Exhibit (Exh.) MAC-A. In its referral, CMS asserts that there is an error of law material to the outcome of the claims and that the decision is not supported by a preponderance of the evidence. Exh. MAC-A. More specifically, CMS maintains that the ALJ erred in setting aside the extrapolated overpayment and by finding that Medicare is time-barred from recouping overpayments for services that occurred in 2005. *Id.*

The appellant, through counsel, timely-filed his exceptions to the CMS referral. The Council enters the appellant's exceptions into the record as Exhibit MAC-B. The appellant contends that the Council should not accept own motion review of the ALJ's decision because the same issues were previously considered by the Council and resolved by the ALJ on remand, the ALJ completed the record as required by the Council's prior remand order, and the ALJ's decision is supported by a preponderance of the evidence of record and does not contain errors of law. Exh. MAC-B. Additionally, the appellant requests "a declaration that no additional requests for review from the QIC will be considered." *Id.* at 6.

After considering the record before the ALJ, the contentions presented in CMS' referral memorandum, and the appellant's response to the referral, the Council finds that the ALJ erred by invalidating the statistical sample in this case, and by waiving the appellant's liability for all overpayments made on January 1, 2005, through August 28, 2005. Accordingly, the Council hereby reverses the ALJ's decision in part to uphold the use of statistical sampling and extrapolation in this case and to find the appellant liable for all overpayments pursuant to section 1870 of the Act.

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<sup>1</sup> The ALJ's decision includes a spreadsheet listing 108 beneficiaries. Dec. 2 attachment. The CMS list of beneficiaries identifies only 103 beneficiaries. Exh. MAC-A at 16-18. It appears that CMS seeks review of some, but not all, of the ALJ's unfavorable coverage determinations below. Compare Exh. MAC-A at 16 with Dec. 2 attachment at 5-6 (CMS seeks review of the claims arising from beneficiary P.B., for which the ALJ denied coverage below), 8-10 (CMS does not seek review of the claims arising from beneficiaries B.B.B. and J.C., for which the ALJ denied coverage below).

## BACKGROUND AND PROCEDURAL HISTORY<sup>2</sup>

On or about August 29, 2005, Hurricane Katrina flooded and destroyed the appellant's outpatient clinic located in the lower Ninth Ward of New Orleans, Louisiana. ALJ Master File, File 3C,<sup>3</sup> Exh. 1 (Exh. 1) at 54-55; CD recording of August 11, 2010, ALJ Hearing (ALJ Hearing 1) at 11:52-12:00, 1:00-1:20. Two months later, the appellant reopened the clinic in a new location in New Orleans. *Id.* In May 2007, the appellant decided to close the clinic and notified CMS. *Id.* In June 2007, he informed patients that the clinic was closing, by letter. *Id.*; see also Exh. 1 at 106. In August 2007, the appellant packed his medical records for storage, and relocated to Texas. *Id.*

By letter dated September 10, 2007, the ZPIC Benefit Integrity Unit<sup>4</sup> initiated an audit of the appellant's billing in calendar years 2005 and 2006. Exh. 1 at 54-55, 101-02; ALJ Hearing 1 at 1:00-1:20 PM. Although the ZPIC mailed this letter to the address of the appellant's closed clinic in New Orleans, he was able to receive it. *Id.*

The appellant responded to the request for a substantial number of medical records approximately 35 days later. *Id.* Subsequently, the ZPIC sent a letter requesting signature and initial exemplars for the clinic's former staff members to the address of the closed clinic. Exh. 1 at 178-79. The appellant asserts that he did not receive that letter. ALJ Hearing 1 at 1:00-1:20; see also Exh. 1 at 54-55 (timeline). The appellant did not receive any further information or contact from the ZPIC or CMS for more than 17 months. *Id.* Then, on March 19, 2009, the ZPIC sent written notice of the audit results to the appellant at his Texas address. Exh. 1 at 119-75. The ZPIC informed the appellant that it had identified an extrapolated overpayment of \$2,467,432.00, arising from his claim submissions in 2005 and 2006. *Id.* at 126.

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<sup>2</sup> In describing the background and procedural history of this case, the Council relies heavily upon its earlier description of the same in its February 18, 2011, remand order.

<sup>3</sup> As noted in our prior remand, the ALJ's Master File numbered 3 of 3 originally consisted of an oversized, white 3-ring binder. The rings in this binder broke, so the Council transferred the documents to four medium-sized black binders, labeled as Master Files 3A, 3B, 3C, and 3D.

<sup>4</sup> AdvanceMed, a Medicare contractor originally known as a Program Safeguard Contractor (PSC) and now referred to as ZPIC, conducted the audit at issue.

On April 30, 2009, the appellant requested redetermination, and included initial medical records and rebuttals on the individual claims. Exh. 1 at 75-86; ALJ Hearing 1 at 1:20-1:30. In the redetermination request, the appellant made clear that, because of the volume of claims involved, he would also be submitting additional information and documentation, as permitted by the regulations. *Id.*; see also 42 C.F.R. §§ 405.946(b), 405.950(b)(3). However, the contractor issued the redetermination approximately 47 days later, before the appellant submitted the additional information and documentation. Exh. 1 at 44-45, 61. The contractor's redetermination was wholly unfavorable to the appellant. *Id.*

On December 11, 2009, the appellant requested reconsideration, and included rebuttals and supporting documentation for the denied claims. *Id.* at 36-53. On February 10, 2010, the Qualified Independent Contractor (QIC) issued a partially favorable decision (including a 51-page spreadsheet providing a specific rationale or finding for each claim). Exh. E at 16-93. The QIC found that Medicare covered some, but not all, of the claims at issue. *Id.* The QIC also reviewed and rejected the appellant's challenges to actions taken by the ZPIC, including its statistical methodology. *Id.* at 16-42.

The appellant then requested an ALJ hearing. The appellant submitted additional information regarding the claims, including medical records, billing code explanations, and rebuttals (Exh. B, 147 pages); Medicare provider numbers and treating physician handwriting and signature samples (Exh. C, 59 pages); and CPT code descriptions, materials from national and local coverage determinations (Exh. D, 108 pages). As part of the hearing process, the ALJ conducted a pre-hearing teleconference with the appellant's counsel and a representative of the ZPIC on June 22, 2010. The ALJ also conducted an in-person hearing on August 11, 2010, with the appellant, his counselors, and his expert witness. The ZPIC had an opportunity to participate in the August 11, 2010, hearing but declined to do so. The ZPIC instead filed a post-hearing position paper with the ALJ, which did not address the merits of the individual claims in the sample. See Exh. A at 20-44.

Subsequently, on September 24, 2010, the ALJ issued a partially favorable decision under ALJ appeal number 1-587559636, adjudicating a number of factual and legal issues.<sup>5</sup> In that

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<sup>5</sup> The Council will refer to the ALJ's September 24, 2010, decision as Decision 1.

decision, the ALJ held that the Secretary's section 1135 waiver, based upon documentation difficulties for health care providers affected by Hurricane Katrina, applied to this case to remove the dates of service from August 29, 2005, through January 31, 2006, from consideration and to exclude them from the overpayment determination. Dec. 1 at 11. The ALJ found moot any alleged violations of the appellant's procedural and due process rights based upon the ZPIC's and the contractor's actions because the ALJ found good cause to admit into evidence all of the appellant's submissions and conducted a *de novo* review of all evidence as required by the regulations. *Id.* at 12-13. The ALJ also determined that the ZPIC's delay in performing its duties and identifying the overpayment denied the appellant the opportunity to correct his billing errors, and that such action constituted a material violation of due process and warranted "dismissal of any alleged financial liability." *Id.* at 13-14.

Regarding the use of statistical sampling, the ALJ determined that: the ZPIC's original calculation of a 100 percent error rate is inaccurate, given the QIC's subsequent coverage reversals; after stratifying the universe and sample based on dollar amounts, the ZPIC disproportionately sampled from, and extrapolated to, the strata with the substantially larger dollar amounts; and the ZPIC did not include paid claims equal to zero in its universe, frame or sample. *Id.* at 14-17. The ALJ concluded that the ZPIC's sampling methodology was not representative and was therefore invalid, and that the extrapolated overpayment must be set aside *in toto*. *Id.* at 17.

The ALJ then conducted a detailed review of the 108 individual claims comprising the sample, based on medical records, the appellant's rebuttal statements, hearing testimony, National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) submitted, and signature and authentication requirements and evidence, where applicable. See Dec. 1 at 17-19 and attached spreadsheet (54 pages); see also Exh. D (provisions from the NCD Coding Policy Manual and various LCDs). The ALJ also determined that the appellant did not receive incorrect, or double, payments as the result of an alleged billing software error. Dec. 1 at 19.

Turning to liability, the ALJ discussed the applicability of section 1879 of the Act and concluded that the appellant, and not the individual beneficiaries, was liable for any non-covered services. *Id.* at 20. The ALJ's discussion of section 1870 of

the Act did not fully distinguish between the provisions of sections 1870(b) and 1870(c). The ALJ found that, because the evidence did not show that the appellant was at fault, the appellant was entitled to a waiver of Medicare's recovery for overpayments for services with dates of service January 1, 2005, through January 1, 2006. *Id.* at 20-22. In doing so, the ALJ held that the term "fault" implies an error in medical judgment below the standard expected of the profession, i.e., negligence or intentional misconduct. The ALJ also found that the appellant remained liable for any actual overpayments arising from the sample claims for payments made on February 1, 2006, through December 31, 2006. *Id.*

By memorandum dated November 22, 2010, CMS sought own motion review. Exh. MAC-1. CMS asserted that the ALJ erred in finding that section 1135 shielded the appellant's claims arising from dates of service on August 29, 2005, through January 31, 2006, from review because the appellant did not specifically request, nor was he granted, such a waiver and because many of the bases for denial were unrelated to the hurricane. *Id.* at 10-13. CMS also asserted that the ALJ erred in determining that the ZPIC's failure to notify the appellant of the overpayment within 60 days of receiving his medical records constitutes a material violation of due process rights and that enforcing the extrapolated overpayment in this context would be unconstitutional. *Id.* at 13-15. Next, CMS contended that the ALJ erred when he held the statistical sample invalid and set aside the extrapolated overpayment. *Id.* at 15-17. CMS also objected to the ALJ waiving Medicare's recoupment based upon section 1870(c)'s "against equity and good conscience language" and a three-year time restriction. *Id.* at 17-19. Finally, CMS took issue with the ALJ's favorable coverage determinations and summarily asserts that they are not supported by the preponderance of evidence in the record. *Id.* at 19.

The appellant filed exceptions to the referral, requesting that the Council decline own motion review on the basis that the ALJ's decision did not contain material errors of law and was supported by a preponderance of evidence in the record. The appellant specifically asserted that: he was entitled to the benefit of the section 1135 waiver due to Hurricane Katrina; his due process rights have been repeatedly violated; the extrapolation is invalid; Medicare is barred from recovering the overpayments made in 2005; and a new hearing would be unnecessary and inappropriate.

On February 18, 2011, and under docket number M-11-358, the Council issued an order vacating the ALJ's decision and remanding the case to the Office of Medicare Hearings and Appeals (OMHA) for further proceedings, including a supplemental hearing and a new decision. See generally Remand Order (Order). The Council accepted own motion review of the ALJ's September 24, 2010, decision on the bases that it contained legal error material to the outcome of the claims and was not supported by a preponderance of the evidence. *Id.* at 1. The Council's order held that the ALJ did not err in removing the August 29, 2005, through January 31, 2006, dates of service from audit consideration because the Secretary declared a state of emergency as a result of Hurricane Katrina. *Id.* at 7-9. The Council further explained that when those dates of service are removed from audit consideration, they also must be excluded from the overpayment determination (including the sample, the frame, and the universe). *Id.*; see also Dec. 1 at 11. The Council then rejected CMS' contention that the ALJ's coverage determinations be vacated, reheard, and re-decided due to an error of law. *Id.* at 9-10. The Council specifically ruled that, on remand, the ALJ need not re-adjudicate the 108 sample claims because, on the face of his analysis, it appears that the ALJ fully and fairly adjudicated the individual claims.

The Council, however, determined that remand was necessary in this instance because it was unable to review the ALJ's rulings on sampling and extrapolation methodology because the compact disc or discs containing the primary evidence of the statistical sample and methodology was (were) not present in the record in an accessible format. *Id.* at 10-15. The Council also identified additional evidentiary deficiencies, mainly relating to the location and labeling of attachments to various submissions. *Id.* The Council also found that the ALJ did not state or apply the correct standards for waiving Medicare's recovery of an overpayment under section 1870 of the Act. *Id.* at 15-17. Finally, the Council determined that the ALJ erred in finding that the ZPIC violated the appellant's due process rights and that the violation warranted a dismissal of any alleged financial liability. *Id.* at 17-20.

On remand, the OMHA re-docketed the case as ALJ appeal number 1-740993021.<sup>6</sup> The ALJ conducted a supplementary hearing with the appellant's counsel and ZPIC representatives on April 28, 2011. On July 14, 2011, the ALJ issued another partially favorable decision. In that decision, the ALJ stated that he admitted all

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<sup>6</sup> The Council will refer to the ALJ's July 14, 2011, decision as Decision 2.

documentation identified in the Council's remand order into evidence as Exhibits AA through EE, thereby completing the record.<sup>7</sup> Dec. 2 at 3. The ALJ incorporated by reference his previous determinations regarding the waiver of any overpayments arising from claims paid on August 29, 2005, through January 31, 2006, pursuant to section 1135 due to Hurricane Katrina; the individual coverage determinations on the sample claims set forth in the 54-page spreadsheet attachment; and the limitation on liability pursuant to section 1879 of the Act, holding the appellant liable for all non-covered costs. *Id.*

The ALJ then considered the use of statistical sampling in this case. While conceding that the Act prohibits review of the Secretary's (and, by delegation, the contractor's) determination of sustained or high levels of payment errors, the ALJ offered a discussion on the matter as *dicta*. *Id.* at 11-12. The ALJ once again found persuasive the appellant's expert witness testimony and determined that the statistical sample was not representative, and is therefore invalid, because the ZPIC disproportionately increased the number of claims in each stratum to 30 and did not include underpayments in its calculations. *Id.* at 12-13. The ALJ also determined that the dates of service from August 29, 2005, through January 31, 2006, were incorrectly included in the audit, pursuant to the Secretary's section 1135 waiver. *Id.* at 13. The ALJ concluded by invalidating the statistical sample and extrapolated overpayment *in toto*. *Id.*

Turning to section 1870's waiver of liability, the ALJ determined that Medicare was time-barred from recovering any overpayments arising from dates of service on January 1, 2005, through August 28, 2005, because the ZPIC did not notify the appellant of the overpayment until more than three years later, in 2009. *Id.* at 16. The ALJ concluded by holding the appellant liable for any actual payments received in error for services on February 1, 2006, through December 31, 2006. *Id.*

By memorandum dated September 9, 2011, CMS sought own motion review of the ALJ's second decision on the bases that there is an error of law material to the outcome of the claims and that the decision is not supported by a preponderance of the evidence. Exh. MAC-A. CMS limited its request to those dates

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<sup>7</sup> Solely for ease of reference, the Council has printed out select portions of the compact disc located at exhibit EE, mainly from Attachment 9, and filed them with the disc. These documents are therefore duplicative of information already present in the record on the disc.

of service prior to August 29, 2005, and after January 31, 2006. *Id.* at 10. In its referral memorandum, CMS asserts that the ALJ erred in setting aside the extrapolated overpayment because the appellant's arguments are wholly speculative and not supported by the evidence of record. *Id.* at 11-14. CMS further contends that the appellant's assertion (which the ALJ found persuasive) that increasing the number sampled from any strata misrepresents the final overpayment does not reflect the methodology actually used by the ZPIC in this instance. *Id.* Finally, CMS asserts that the ALJ erred in finding that Medicare is time-barred from recouping overpayments arising from January 1, 2005, through August 28, 2005, dates of service. *Id.* at 14-15. CMS explains that regardless of when an overpayment is assessed, the waiver provisions require a "without fault" analysis. *Id.*

As noted above, the appellant filed exceptions to the CMS referral. Exh. MAC-B. The appellant contends that the Council should not accept own motion review of the ALJ's decision because the same issues were previously considered by the Council and resolved by the ALJ on remand; the ALJ completed the record as required by the Council's prior remand order; and the ALJ's decision is supported by a preponderance of the evidence of record and does not contain errors of law. *Id.* The appellant also requests "a declaration that no additional requests for review from the QIC will be considered." *Id.* at 6.

The Council will consider the issues raised by both CMS and the appellant, in turn, below.

## DISCUSSION

### A. Own Motion Review

In response to the CMS referral, the appellant requests that the Council decline own motion review because the ALJ's decision is supported by a preponderance of the evidence and does not contain legal error. Exh. MAC-B. The appellant also questions CMS' ability to file an additional referral in this case because the same issues were previously considered by the Council on own motion review and resolved by the ALJ on remand. *Id.*

If, as here, CMS or its contractor participated in an appeal at the ALJ level, the Council exercises own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ, the decision is not consistent with the preponderance of the evidence of record, or there is a

broad policy or procedural issue that may affect the general public interest. 42 C.F.R. § 405.1110(c)(1). In deciding whether to accept review under this standard, the Council limits its consideration of the ALJ's action to those exceptions raised by CMS. *Id.* In this case, the CMS referral clearly identifies specific errors of law material to the outcome of the case, namely the ALJ's invalidation of the statistical sample and his application of section 1870 of the Act to the facts of this case. Exh. MAC-A. The Council therefore accepts own motion review on this basis. 42 C.F.R. § 405.1110(c)(1).

Moreover, the regulation provides that "CMS or any of its contractors may refer a case to the [Council] for it to consider under this authority anytime within 60 calendar days after the date of an ALJ's decision or dismissal." 42 C.F.R. § 405.1110(a). The regulations do not include any limiting or qualifying language that would tend to restrict CMS from filing a second referral for own motion review in the same case. The Council previously vacated the ALJ's first decision, and, on remand, the ALJ issued a new decision dated July 14, 2011. CMS then requested own motion review of the ALJ's new decision within 60 calendar days of its issuance. Exh. MAC-A. The appellant has not cited any authority to support his assertion that CMS cannot seek own motion review of a newly issued ALJ decision, albeit for a second time in the same case. The Council therefore finds no basis for denying CMS' request for own motion review in this case.

Finally, the appellant requests "a declaration that no additional requests for review from the QIC will be considered." *Id.* at 6. The Council is unaware of, and the appellant has not identified, any legal or program authority permitting it to make such a declaration. Procedurally, however, the appellant should be aware that this decision is final and binding on all parties unless a Federal district court issues a decision modifying the Council's decision or the decision is revised as a result of a reopening. 42 C.F.R. § 405.1130. "A party may file an action in a Federal district court within 60 calendar days after the date it receives notice of the [Council]'s decision." *Id.*

#### B. Statistical Sampling Methodology

CMS (formerly HCFA) Ruling 86-1 describes the agency's policy on the use of statistical sampling to project overpayments to Medicare providers and suppliers. The Ruling also outlines the history and authority, both statutory and precedential, for the

use of statistical sampling and extrapolation by CMS in calculating overpayments. We incorporate that discussion by reference here. In part, the Ruling provides:

Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

CMS Ruling 86-1-9 & 86-1-10.

CMS's sampling guidelines are found in chapter 8 of CMS's Medicare Program Integrity Manual (MPIM), Pub. 100-08. The guidelines reflect the perspective that the time and expense of drawing and reviewing the claims from large sample sizes and finding point estimates which accurately reflect the estimated overpayment with relative precision may not be administratively or economically feasible for contractors performing audits. Instead, the guidelines allow for smaller sample sizes and less precise point estimates, but offset such lack of precision with direction to the carriers to assess the overpayment at the lower level of a confidence interval - generally, the lower level of a ninety-percent one-sided confidence interval. This results in the assumption, in statistical terms, that there is a ninety-percent chance that the actual overpayment is higher than the overpayment which is being assessed, thus giving the benefit of the doubt resulting from any imprecision in the estimation of the overpayment to the appellant, not the agency. As a result of the above policy decision, the question becomes whether the sample size and design were sufficiently adequate to provide a meaningful measure of the overpayment, and whether the provider is treated fairly despite any imprecision in the estimation.

The MPIM provides guidance to contractors in conducting statistical sampling for use in estimating overpayment amounts. The instructions are intended to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project overpayments where review of claims indicates that overpayments have been made. The MPIM describes the purpose of its guidance as follows:

These instructions are provided so that a sufficient process is followed when conducting statistical sampling to project overpayments. Failure by the PSC or the ZPIC BI unit or the contractor MR unit to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment. An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. **Failure by the PSC or ZPIC BI units or the contractor MR units to follow one or more requirements may result in review by CMS of their performance, but should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment.**

MPIM, Ch. 8 at § 8.4.1.1 (emphasis added).

The MPIM further provides that a contractor may employ any sampling methodology that results in a "probability sample." *Id.* at § 8.4.2. The MPIM explains the two features required for a procedure to be classified as probability sampling, and explains that:

If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made. In other words, a probability sample and its results are always "valid." Because of differences in the choice of a design, the level of available resources, and the method of estimation, however, some procedures lead to higher precision (smaller confidence intervals) than other methods. A feature of probability sampling is

that the level of uncertainty can be incorporated into the estimate of overpayment as is discussed below.

*Id.*

Thus, the Council need not find that CMS or its contractor undertook statistical sampling and extrapolation based on the most precise methodology that might be devised in order to uphold an extrapolated overpayment based on that methodology. Rather, as the above-quoted authorities make clear, the test is simply whether the methodology is statistically valid.

The ALJ found the statistical sample invalid because it was not representative and because the ZPIC did not include underpayments in its calculation. Dec. 2 at 12-13. In its referral memorandum, CMS asserts that the applicable guidance, including CMS Ruling 86-1 and the MPIM, establishes that the reasons cited by the ALJ in support of his decision to invalidate the sampling methodology, do not, in fact, demonstrate that the methodology is invalid. Exh. MAC-A at 11-14. The appellant asserts that the ALJ relied on extensive, unrebutted expert testimony in setting aside the extrapolated overpayment. Exh. MAC-B. After considering the evidence of record, the ALJ's reasoning and the parties' respective assertions, the Council finds the ZPIC's sampling methodology valid in this instance.

In this case, the ALJ found "particularly compelling" the appellant's expert witness<sup>8</sup> testimony and held that the ZPIC:

disproportionately increased the number of claims to 30 in each stratum, thereby materially deviating and altering the sample recommended by RAT-STATS. The usual consequence of unevenly changing proportionality of the sampled strata results in a misrepresentation as it applied to the frame, when then projected out to the universe. The effect in this particular case was an overestimation of the percentage of paid claims in Strata #4 (representing the highest claim dollar amount), and an underestimate of claims in Strata #1 (representing the lowest claim dollar amount).

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<sup>8</sup> While the ALJ qualified the appellant's witness as an "expert" and the witness attested to her involvement in numerous trials and administrative proceedings, the witness earned her graduate degrees in experimental psychology and human experimental psychology, not statistics. Exh. A at 70.

Dec. 2 at 12 (internal citations omitted).

The appellant's position, which the ALJ essentially adopted, seems to be that the ZPIC's unexplained deviation from the RAT-STATS recommended sample size for each strata alone renders the sample invalid. Exh. A at 12. The appellant also asserts the ZPIC's actions resulted in a "grossly inflated" overpayment amount, such that the overpayment amount per claim was "over 2.25 times larger" than the "average value of the claim." *Id.* at 12-13.

The MPIM recognizes that a number of sampling designs are acceptable, including: simple random sampling, systematic sampling, stratified sampling, and cluster sampling, or a combination of these. MPIM, Ch. 8 at § 8.4.4.1. Stratified sampling is a design that "involves classifying the sampling units in the frame into non-overlapping groups or strata. The objectives are to "define the strata in a way that will reduce the margin of error in the estimate below that which would be attained by other sampling methods, as well as to obtain an unbiased estimate or an estimate with an acceptable bias." *Id.* at § 8.4.4.1.3. "[T]he independent random samples from the strata need not have the same selection rates." *Id.* As CMS explained, the ZPIC in this instance "used a stratified sampling design with four strata distinguished by 'paid amount division points' and increased the number of samples in each stratum to 30." Exh. MAC-A at 11 (citing Exh. 1 at 137). The MPIM clearly states that disproportionate stratified random sampling does not bias or invalidate the results:

Given the definition of a set of strata, the designer of the sample must decide how to allocate a sample of a certain total size to the individual strata. In other words, how much of the sample should be selected from Stratum 1, how much from Stratum 2, etc.? As shown in the standard textbooks, there is a method of "optimal allocation," i.e., one designed to maximize the precision of the estimated potential overpayment, assuming that one has a good idea of the values of the variances within each of the strata. Absent that kind of prior knowledge, however, **a safe approach is to allocate proportionately.** That is, the total sample is divided up into individual stratum samples so that, as nearly as possible, the stratum sample sizes are in a fixed proportion to the sizes of the individual stratum frames. **It is emphasized, however, that even**

**if the allocation is not optimal, using stratification with simple random sampling within each stratum does not introduce bias,** and in almost all circumstances proportionate allocation will reduce the sampling error over that for an unstratified simple random sample.

MPIM, Pub. 100-08, Ch. 8 at § 8.4.11.1; see also Exh. CC at 21 (ZPIC's post-hearing position paper).

As ably explained in the referral memorandum:

The ALJ's decision is contrary to Medicare policy which indicates that disproportionate allocation does [not] render the sample invalid. The ALJ cited no authority to support his conclusion that the sampling methodology is invalid because the ZPIC "deviated" from the RAT-STATS recommended sample size by *increasing* the number of claims in each stratum to 30. Neither CMS Ruling 86-1 nor the MPIM indicates that having a disproportionate number of claims in each stratum would invalidate the sample.

Additionally, the appellant's assertion that the sample mean and projected overpayment amount were inflated is not supported by the evidence of record. [The ZPIC]'s sampling methodology memorandum states that, after reviewing each sampled claim, "a *weighted* average overpayment was calculated and multiplied by the total number of claims in the combined frames."

Exh. MAC-A at 12 (citing Exh. 1 at 138).

The appellant's expert witness testimony, on which the ALJ relied, opined that the ZPIC erred in increasing the total sample from 30 as recommended by RAT-STATS, distributed proportionally across four strata, to a total of 120, with each strata containing 30 sampling units. See, e.g., Exh. CC at 399 and Exh. FF. In turn, the appellant's expert witness asserted that the ZPIC could not weight the strata results when the overpayment was computed to account for this variation.

The ZPIC responds that this assertion is "absolutely false." Exh. FF at 29. CMS asserts that, by weighting the results, the average overpayment in each stratum is proportional to the number of services in that stratum and, therefore, is

representative of the frame. Exh. MAC-A at 13. In this case, when the stratified samples were projected to the universe, they were disproportionately weighted to correct for the issue identified by the appellant's expert witness. If anything, the disproportionate stratification at issue produced a more precise calculation of Medicare's estimated overpayment. See also Exh. CC at 20-22.

We find that the ZPIC's evidence, including details of the point estimate calculation, precision percent, and relative sampling error, is consistent with the MPIM, as well as inherently more reliable and persuasive than the hazy and obfuscatory assertions of appellant's expert witness.

The ALJ also took issue with the ZPIC's failure to include underpayments in addition to overpayments in order to offset any amounts due. Dec. 2 at 13. However, the MPIM defines the "Composition of the Universe" for Part B claims as follows:

The universe **shall consist of all fully and partially paid claims submitted by the supplier for the period selected for review and for the sampling units to be reviewed.** For example, if the review is of Physician X for the period January 1, 2002 through March 31, 2002, and laboratory and other diagnostic tests have been selected for review, the universe would include all fully and partially paid claims for laboratory and diagnostic tests billed by that physician for the selected time period.

MPIM, Ch. 8 at § 8.4.3.2.1 (emphasis added). The ZPIC defined its sampling universe as non-Medicare secondary payer claims "with at least one line of service paid >0 to provider." Exh. 1 at 136. Thus, the ZPIC properly composed the universe of fully and partially paid claims in accordance with the manual guidance. The ALJ erred in opining otherwise.

Finally, the ALJ's decision also seems to incorporate the ZPIC's inclusion of dates of service covered by the Secretary's section 1135 waiver as an additional basis for invalidating the sample. Dec. 2 at 13. However, the MPIM instructs that, "[i]f the decision on appeal upholds the sampling methodology but reverses one or more of the revised initial claim determinations, **the estimate of overpayment shall be recomputed and a revised projection of overpayment issued.**" MPIM, Ch. 8 at § 8.4.9.2 (emphasis added). Thus, the Council clarifies that the

appropriate remedy for the ZPIC's action is not to invalidate the sample or set aside the use of extrapolation, but to remove the August 29, 2005, through January 31, 2006, dates of service from audit consideration and exclude them from the overpayment determination (and thus, exclude them from the sample, the frame, and the universe).

For the reasons explained above, the Council concludes that the ALJ erred in finding the ZPIC's sampling methodology and overpayment extrapolation invalid. While we reverse the ALJ on these points, we do not disturb the ALJ's individual coverage determinations regarding the sample claims. See Dec. 2 at 16; Dec. 2 Attachment at 1-54.

### C. Waiver of Overpayment Recovery

After considering the medical necessity of each of the sample claims and determining that Medicare does not cover some of the services at issue, the next inquiry is whether the appellant and/or the beneficiaries are entitled to a limitation on liability pursuant to section 1879 of the Act. If, as here, the ALJ determines that the provider is liable for the non-covered services and an overpayment continues to exist,<sup>9</sup> then the next inquiry becomes whether the provider is entitled to a waiver of Medicare's recovery pursuant to section 1870 of the Act.

Before the Council, CMS asserts that the ALJ erred in finding that Medicare is essentially time-barred from recovering any overpayment arising from claims with dates of service on January 1, 2005, through August 28, 2005. Exh. MAC-A at 14-15.

In response, the appellant maintains that the ALJ properly determined he was "without fault" for the overpayments arising from January 1, 2005, through August 28, 2005, dates of service. Exh. MAC-B. Specifically, the appellant asserts that Medicare coverage was eventually granted for many sample claims so there is no evidence of a pattern of billing for services that the appellant should have known were not covered. *Id.*

The ALJ determined that, because the ZPIC notified the appellant of the overpayment in 2009, Medicare cannot recoup any overpayments arising from payments made on January 1, 2005,

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<sup>9</sup> A supplier may have "knowledge," in part, based on its written notice of non-coverage to the beneficiary or its own experience, actual notice, or constructive notice. 42 C.F.R. § 411.406; see also Medicare Claims Processing Manual (MCPM), CMS Pub. 100-04, Ch. 30 at § 40.1.

through August 28, 2005. Dec. 2 at 16. In reaching this conclusion, the ALJ essentially applied a three-year statute of limitations to Medicare's recovery, which he based on section 1870 of the Act. This constitutes material legal error.

Section 1870 of the Act governs the recovery of overpayments, based upon provider or beneficiary fault. Section 1870(b) allows for a waiver of recovery of an overpayment to a provider if it is without fault in incurring the overpayment. Section 1870(b) of the Act effectively presumes no fault on a provider's part where an overpayment determination is made "subsequent to the third year following the year in which notice was sent to such individual that such amount had been paid" in *the absence of evidence to the contrary*. CMS has provided guidance on this issue in its Medicare Financial Management Manual (MFMM). For overpayments found after the third calendar year after the year of payment, the MFMM indicates:

There are special rules that apply when an overpayment is discovered subsequent to the third year following the year in which notice was sent that the amount was paid. **Ordinarily**, the provider or beneficiary will be considered without fault **unless there is evidence to the contrary**. In the absence of evidence to the contrary, the FI [fiscal intermediary] or carrier will not recover the determined overpayment. (**One example of evidence to the contrary would be a pattern of billing errors**. See PIM, Chapter 3.)

MFMM, Pub. 100-06, Ch. 3, § 80 (emphasis added). The MFMM also provides guidance on calculating the "third year" after the year payment was approved. It states:

Only the year of the payment and the year it was found to be an overpayment enter into the determination of the 3-year calendar period. The day and month are irrelevant. [For example,] [w]ith respect to payments made in 2000, the third calendar year thereafter is 2003.

MFMM, Ch. 3 at § 80.1.

In essence, section 1870(b) of the Act and the MFMM create a rebuttable presumption that providers are "without fault" for overpayments discovered more than three calendar years after the

year in which the initial determination was made. Although the precise date of the contractor's initial determination of each claim is unclear from the current record, it could not have occurred any earlier than January 1, 2005, because the dates of service at issue are January 1, 2005, through December 31, 2006. The ZPIC first determined that there had been an overpayment in 2009, after the third calendar year following the initial payment. Therefore, the aforementioned presumption applies to the present case.

Section 1870(b) does not define the meaning of the term "without fault." However, a provider is without fault if it exercised reasonable care in billing and accepting Medicare payment. MFMM, Ch. 3 at § 90. A provider is considered not "without fault" if, e.g., it did not submit documentation to substantiate that services billed were covered, or billed, or Medicare paid, for services the provider should have known were not covered. *Id.* at § 90.1.

The MFMM also provides that, generally, a provider's allegation that it was not at fault with respect to payment for noncovered services because it was not aware of coverage requirements is not considered a basis for finding it "without fault" if one of several conditions is met. One such condition is if the provider billed, or Medicare paid for, services the provider should have known were not covered. *Id.* The MFMM further explains that the provider should have known about a policy or rule if the policy or rule is in the provider manual or in the regulations. *Id.* In this case, the ALJ's determined that the appellant is not entitled to a limitation on liability pursuant to section 1879 of the Act based on his constructive knowledge of Medicare coverage guidelines. See Dec. 2 at 16; Dec. 1 at 20. As a result of this determination, the ALJ should have also found that the appellant did not exercise reasonable care in billing as he knew, or should have known, that Medicare would not cover the services as billed. The appellant thus cannot be "without fault."

Having considered the basis on which the overpayment was found in this case, section 1870(b) of the Act, and the guidance set forth in the MFMM, the Council finds that the ALJ erred in finding the appellant "without fault" for Medicare's overpayment arising from payments occurring January 1, 2005, through August 28, 2005. As the appellant was not "without fault" in creating the overpayment, a waiver of recovery of the overpayment is not warranted.

**DECISION**

The Council reverses the ALJ's decision, in part, to uphold the ZPIC's use of statistical sampling in this case, and to find the appellant liable for those overpayments arising from dates of service occurring January 1, 2005, through August 28, 2005, as well as from February 1, 2006, through December 31, 2006. Upon effectuation, the contractor shall recalculate the extrapolated overpayment, taking into account those claims which must be excluded pursuant to a section 1135 waiver, as well as the QIC's and the ALJ's individual favorable coverage determinations. The appellant remains liable for the recalculated, extrapolated overpayment plus any accrued interest.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki  
Administrative Appeals Judge

/s/ Susan S. Yim  
Administrative Appeals Judge

Date: December 07, 2011